

JAN - 6 2000

K993948

9. 510(K) SUMMARY

Submitted By:

Neal E. Fearnot, Ph.D.
President
Cook Biotech, Incorporated
3055 Kent Avenue
West Lafayette, IN 47906
(765) 497-3355

November 18, 1999

Device:

| | |
|-------------------------------|------------------------|
| Trade Name: | SIS Wound Dressing II |
| Common/Usual Name: | Topical Wound Dressing |
| Proposed Classification Name: | Unclassified (79KMF) |

Intended Use:

The SIS Wound Dressing II is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), and draining wounds. The device is intended for one-time use.

Predicate Devices:

The SIS Wound Dressing II is similar to predicate collagen-based wound dressings that are currently marketed for the management of wounds including the SIS Wound Dressing (D.C. #K973170) manufactured by Cook Biotech, Incorporated, the FIBRACOL * Plus Collagen Wound Dressing with Alginate (D.C. #K982597) manufactured by Johnson and Johnson Medical, and the SkinTemp® Kollagen Wound Management Material (D.C. #K913023) and Medifil® Kollagen Particles (D.C. #K910944) manufactured by Biocore Medical Technologies.

Device Description:

The SIS Wound Dressing II is primarily composed of porcine collagen that is supplied in sheet form in sizes ranging from 2 x 4 cm to 20 x 40 cm.

Substantial Equivalence:

The SIS Wound Dressing II is similar with respect to indications for use, materials and physical construction to predicate devices in terms of section 510(k) substantial equivalency.

Discussion of Tests and Test Results:

The SIS Wound Dressing II was subjected to a panel of tests to assess biocompatibility. The SIS Wound Dressing II passed the requirements of all tests.

Conclusions Drawn from Tests:

This device is, with respect to intended use and technological characteristics, substantially equivalent to the predicate devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Neal E. Fearnot, Ph.D.
President
Cook Biotech Inc.
3055 Kent Avenue
West Lafayette, Indiana 47906

Re: K993948
Trade Name: SIS Wound Dressing II
Regulatory Class: II
Product Code: KMF
Dated: November 18, 1999
Received: November 22, 1999

Dear Dr. Fearnot:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

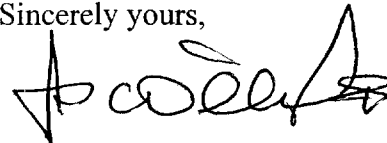
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Neal E. Fearnot, Ph.D.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "J. E. Dillard III", with a stylized flourish at the end.

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 993948Device Name: SIS Wound Dressing II

Indications For Use:

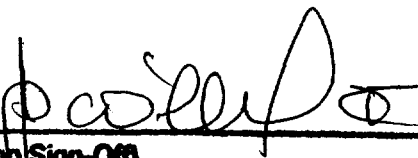
The SIS Wound Dressing II is intended for the management of wounds including:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Tunneled/undermined wounds
- Surgical wounds (donor sites/grafts, post-moh's surgery, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears)
- Draining wounds.

The device is intended for one-time use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993948

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)